K062886

510(k) Summary of Safety and Effectiveness

CAO GROUP
4628 West Skyhawk Drive
West Jordan, UT 84084
Tel: 801.256.9282 Fax: 801.256.9287
www.caogroup.com
Robert K. Larsen, Operations Director
Preparation Date: November 3, 2006

NOV - 6 2006

Device Name:

Trade Name:	Ascent Pit & Fissure Sealant
Common Name:	Pit and Fissure Sealant
Product Classification:	Pit and Fissure Sealant and Conditioner (21 CFR 872.3765, Product Code: EBC)

Legally Marketed Predicate Devices for Substantial Equivalence:

- Clinpro Sealant, Manufactured by 3M Company
  510(k) Number: K992326
- Seal-Rite Pit and Fissure Sealant, Manufactured by Pulpdent Corp.
  510(k) Number: K963921

Rationale for Substantial Equivalence:

The aforementioned device shares similarities for use in the oral cavity for the purpose of sealing pits and fissures in teeth. This device features similar composition, indications for use, and application methods.

Description of Submitted Device:

The Ascent Pit & Fissure Sealant System is a comprehensive light-cured system designed to fill and seal the pits and fissures of teeth. The integrated nano-filler technology provides excellent wear and strength properties. The methacrylate based resin system provides an excellent seal and superior adhesion to etched enamel. The system may alternately be supplied either with or without a pretreatment phosphoric acid etchant. See also Part 6: Specifications

The modification made to the device as originally submitted is the addition of a secondary material in the form of a fluoride releasing compound.

Intended Uses of the Ascent Pit & Fissure Sealant System:

The Ascent Pit & Fissure Sealant System is applied after the intended surface is prepared, etched, and treated as necessary. The material is applied to the site directly from the material packaging, usually in the form of a syringe or other hand-held dispensing apparatus. The sealant is worked into and around the affected area with a tip or brush to ensure an adequate and thorough coat. The material is then polymerized using a suitable dental polymerization light source. This system is marketed and sold only to licensed professional dentists.

Technological Characteristics of Substantial Equivalence:

Both the submitted and predicate devices are composed of similar substances: methacrylate resins, glass particle fillers, and photoinitiators. Additionally, the submitted device and the Clinpro Sealant predicate device contain fluoride releasing agents. Both the submitted and predicate devices are slightly viscous liquids. All have similar methods of application. All are polymerized by dental curing lights.

Performance Standards:

None

Performance Data

See Part 7: Performance Data

Conclusion

The Ascent Pit & Fissure Sealant System as submitted is substantially equivalent to the aforementioned predicate device with regards to purpose of the device, composition, methods of application, and indications for use without raising any new issues regarding safety and/or effectiveness. The device as submitted is identical in Indications for Use, application, labeling – except the addition of reference to the fluoride release compound, and methods of manufacture as compared to the original device submitted and approved under 510(k) Number K053089. The device as submitted is identical in composition in all respects except for the addition of a fluoride releasing compound which serves as a secondary chemical constituent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert K. Larsen
Operations Director
CAO Group Incorporated
4628 West Skyhawk Drive
West Jordan, Utah 84084

NOV - 6 2006

Re: K062886
Trade/Device Name: Ascent Pit and Fissure Sealant
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: September 13, 2006
Received: October 11, 2006

Dear Mr. Larsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062886

Device Name: *Ascent Pit & Fissure Sealant*

Indications For Use:

Ascent Pit & Fissure Sealant is indicated for:

- The sealing of pits and fissures

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) K062886

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.109)